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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/777,727	02/05/2001	Matthew Stewart Platz	66-99A	6079

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EXAMINER

LIU, HONG

ART UNIT

PAPER NUMBER

1624

10

DATE MAILED: 10/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/777,727

Applicant(s)

Platz et al.

Examiner

Hong Liu

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– The MAILING DATE of this communication appears on the cover sheet with the corresponding address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60, 62, and 63 is/are pending in the application.
- 4a) Of the above, claim(s) 1-38 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 62 and 63 is/are allowed.
- 6) ☒ Claim(s) 39-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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DETAILED ACTION

Claims 1-60, 62, and 63 are pending. Claim 61 was canceled

This action is in response to the applicants' amendment and reply filed on August 21, 2002.

Response to Arguments

Applicants' arguments filed on August 21, 2001 have been fully considered with the following effect:

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 39-60 remain rejected under 35 U.S.C. 112, first paragraph, for reasons already made of record notwithstanding applicants' traverse. Applicants argue that terms such as "straight chain or cyclic saccharides", "amino acid groups", "alkylating agents" all have art-recognized meanings. While it might be true that these terms are jargons commonly used among those skilled in the art, the skilled in the art are entitled to know the metes and bounds of the terms to fully appreciate and practice the present invention. The description of the terms in the specification, however, does not seem to provide such knowledge to the skilled in the art. For instance, the specification defines "straight chain or cyclic saccharides" as mono-, di-, and poly-, straight chain and cyclic saccharides. It is well known that polysaccharides are polymers, which, unlike small molecules, can have a molecular weight up to hundreds, if not thousands, of Daltons.

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With such a bulky substituent, it is highly unlikely that the resulting isoalloxazine derivatives would retain their neutralization properties. In fact there is no teaching in the specification that an di- or poly-saccharide substituted isoalloxazine is effective in neutralizing microorganisms in the blood samples. The examples shown in the specification are limited to compounds wherein R1 is a small substituent such as methyl.

Thus, the claims are still not commensurate in scope as to the diversity of Markush groups, straight chain or cyclic saccharides, amino acid groups, alkylating agents which all permit further substitution. The instant case is similar to *In re Lund*, 153 USPQ 625, in which the Court agreed the specific aldehyde reactants mentioned in the specification fell within a limited range and thus far short of the claims' scope. Applicants urge that the compounds embraced herein are active in neutralizing microorganism, and thus all of the functional moieties and heterocyclic/aromatic groups which are embraced by these claims have the activity of neutralizing microorganisms in a fluid. However, no reasons or evidence has been provided to support applicants' position. As was previously mentioned, no compounds of the instant invention are seen to have been tested for their activity against microorganisms. Thus, applicants have not provided adequate information that the instant compounds **as an entire class** have the required activities needed to practice the invention, and therefore, there is no reasonable basis for assuming that the variety of substituents embraced by the claims will all share the same physiological properties. See MPEP 2164.03 for enablement requirements in cases directed to structure-sensitive arts such as the pharmaceutical art. Note also the quote taken from *Surrey*, previously

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cited, "Manifestly, a disclosure which does not adequately establish compounds as useful for an asserted purpose does not adequately describe "how to use" these compounds either." Also note the quote taken from *In re Cavallito* 127 USPQ 202 which was cited in *Surrey*, previously cited, at page 730; "...where the applicant seeks to obtain a monopoly in exchange for his disclosure of a group of compounds there should be a disclosure which gives reasonable assurance that all, or substantially all of them are useful...An applicant is not entitled to a claim for a large group of compounds merely on the basis of a showing that a selected few are useful and a general suggestion of a similar utility in the others." Note *Markush* claims are subject to rejection based upon the lack of supporting disclosure when the "working examples" fail to include written description(s) which teach how to make and use *Markush* members embraced thereby in full, clear and exact terms. See *In re Fouche*, 169 USPQ 429. Furthermore, applicants rely on the working examples in the specification, but as mentioned before, the examples are limited to a homogenous group of compounds. Note *In re Armbruster*, 185 USPQ 152, wherein it was stated that a specification which "describes the invention as broadly as it is claimed...does not necessarily also "enable" one skilled in the art to make or use the claimed invention."

Claims 39-60 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Provisos have been included in the claim. The provisos lack description. Even negative limitations require a description. The MPEP at 2173.05(I) Negative Limitation

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states "Any negative limitation or exclusionary proviso must have basis in the original disclosure. See *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983) *aff'd mem.*, 738 F. 2d 453 (Fed. Cir. 1984)" and further, "Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement." In the instant case, the new concept that has been introduced by the proviso is the specific relationships between R1, R2, R3-R6. This specific relationship of connectivity was previously not disclosed. This notion that the definition of one variable depends on the definitions of other variables is new. The definition of a variable is no longer independent.

1. Rejections to claim 60 under 35 U.S.C. 112, second paragraph is maintained as it is still unclear to the Examiner the metes and bounds of the term "alkylating agent." In claim 39, the metes and bounds of the term "a component" is unknown. In addition "optionally substituted" throughout claim 39 is unclear as to the nature and number of substituent(s) intended. All other rejections under 35 U.S.C. 112, second paragraph are hereby withdrawn in view of the amendment and cancellation of the claims.

Claim Rejections - 35 USC § 102

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2. Rejections to claims under 35 U.S.C. 102 are hereby withdrawn in view of the provisos. In addition, applicants have changed the claims from compound claims to composition claims that include the limitation of a component from the blood constituent.

Claim Rejections - 35 USC § 103

Claims 39-59 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Spencer et al. (US 3,920,650). Applicants' arguments are fully considered but are not found persuasive. Applicants' amended claims recite a composition comprising a component of a biologically active protein and the isoalloxazine compound. Spencer teaches the use of the isoalloxazine compound as antibacterial agents, the process of which involves the formation of a composition of the isoalloxazine compound and the bacteria which contain biologically active protein, including protein the bacteria could secrete into the surrounding environment. Therefore, the claims are still obvious in light of the teaching of the reference.

Claims 39-59 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Petering et al. (US 2,825,729) for the same reasons give above.

Allowable Subject Matter

Claims 62 and 63 are allowable.

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Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Examiner Hong Liu whose telephone number is (703) 306-5814. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at (703) 308-4716. The fax phone number for this group is (703) 308-4734 for "unofficial" purposes and the actual number for **official** business is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose number is (703) 308-1235.

Hong Liu
October 12, 2002


RICHARD L. RAYMOND
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